Complete Summary

GUIDELINE TITLE

Follow-up imaging of bladder carcinoma.

BIBLIOGRAPHIC SOURCE(S)

Jafri SZ, Dinan D, Francis IR, Baumgarten DA, Bluth EI, Bush WH JR, Casalino DD, Curry NS, Israel GM, Kawashima A, Papanicolaou N, Remer EM, Sandler CM, Spring DB, Fulgham P, Expert Panel on Urologic Imaging. Follow-up imaging of bladder carcinoma. [online publication]. Reston (VA): American College of Radiology (ACR); 2007. 9 p. [71 references]

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Segal AJ, Choyke PL, Bluth EI, Bush WH Jr, Casalino DD, Francis IR, Jafri SZ, Kawashima A, Kronthal A, Older RA, Papanicolaou N, Ramchandani P, Rosenfield AT, Sandler CM, Tempany C, Resnick MI, Expert Panel on Urologic Imaging. Follow-up imaging of bladder carcinoma. [online publication]. Reston (VA): American College of Radiology (ACR); 2005. 9 p. [54 references]

The appropriateness criteria are reviewed annually and updated by the panels as needed, depending on introduction of new and highly significant scientific evidence.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Bladder cancer

GUIDELINE CATEGORY

Evaluation
Risk Assessment

CLINICAL SPECIALTY

Nephrology
Oncology
Radiation Oncology
Radiology
Surgery
Urology

INTENDED USERS

Health Plans
Hospitals
Managed Care Organizations
Physicians
Utilization Management

GUIDELINE OBJECTIVE(S)

To evaluate the appropriateness of follow-up radiologic examinations for patients with bladder cancer

TARGET POPULATION

Patients with bladder cancer

INTERVENTIONS AND PRACTICES CONSIDERED

1. X-ray
    - Intravenous urography
    - Chest
    - Abdomen, loopogram
2. Computed tomography (CT)
    - Urography
    - Chest
    - Abdomen and pelvis, with contrast
3. Ultrasound (US), bladder
    - Transabdominal
    - Transurethral
    - Transrectal
4. Magnetic resonance imaging (MRI), abdomen and pelvis
5. Fluorodeoxyglucose positron emission tomography (FDG-PET), whole body

MAJOR OUTCOMES CONSIDERED

Utility of radiologic examinations in the follow-up of patients with bladder carcinoma

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The guideline developer performed literature searches of peer-reviewed medical journals, and the major applicable articles were identified and collected.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Not Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not stated

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

One or two topic leaders within a panel assume the responsibility of developing an evidence table for each clinical condition, based on analysis of the current literature. These tables serve as a basis for developing a narrative specific to each clinical condition.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus (Delphi)

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Since data available from existing scientific studies are usually insufficient for meta-analysis, broad-based consensus techniques are needed for reaching agreement in the formulation of the appropriateness criteria. The American College of Radiology (ACR) Appropriateness Criteria panels use a modified Delphi

technique to arrive at consensus. Serial surveys are conducted by distributing questionnaires to consolidate expert opinions within each panel. These questionnaires are distributed to the participants along with the evidence table and narrative as developed by the topic leader(s). Questionnaires are completed by the participants in their own professional setting without influence of the other members. Voting is conducted using a scoring system from 1 to 9, indicating the least to the most appropriate imaging examination or therapeutic procedure. The survey results are collected, tabulated in anonymous fashion, and redistributed after each round. A maximum of three rounds is conducted and opinions are unified to the highest degree possible. Eighty percent agreement is considered a consensus. This modified Delphi technique enables individual, unbiased expression, is economical, easy to understand, and relatively simple to conduct.

If consensus cannot be reached by this Delphi technique, the panel is convened and group consensus techniques are utilized. The strengths and weaknesses of each test or procedure are discussed and consensus reached whenever possible. If "No consensus" appears in the rating column, reasons for this decision are added to the comment sections.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Criteria developed by the Expert Panels are reviewed by the American College of Radiology (ACR) Committee on Appropriateness Criteria.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

ACR Appropriateness Criteria®

Clinical Condition: Follow-up Imaging of Bladder Carcinoma

Variant 1: Superficial TCC - no invasion or risk factors.

Radiologic Procedure	Rating	Comments	RRL*

Radiologic Procedure	Rating	Comments	RRL*
CT urography	3		Med
X-ray intravenous urography	3	Utilization of intravenous urography has continued to decline with the increasing widespread use of CT urography.	Low
X-ray chest	2		Min
FDG-PET whole body	1		High
US bladder transabdominal	1		None
MRI abdomen and pelvis	1		None
US bladder transurethral	1		None
US bladder transrectal	1		None
CT chest	1		Med
CT abdomen and pelvis	1		High
Rating Scale: 1=Least appropriate, 9=Most appropriate			***Relative Radiation Level**

Note: Abbreviations used in the tables are listed at the end of the "Major Recommendations" field.

Variant 2: Invasive TCC with or without cystectomy.

Radiologic Procedure	Rating	Comments	RRL*
X-ray chest	9		Min
CT urography	8		Med
X-ray abdomen loopogram	8	In patients with an ideal loop post cystectomy.	Low
X-ray intravenous urography	5	Utilization of intravenous urography has continued to decline with the	Low

Radiologic Procedure	Rating	Comments	RRL*
		increasingly widespread use of CT urography.	
MRI abdomen and pelvis	5	See comments regarding contrast in text under "Anticipated Expectations."	None
CT abdomen and pelvis with contrast	5	Appropriate if MDCT urography is not available. Visceral/nodal status evaluated during CT urography.	High
CT chest	3	Performed if chest x-ray is equivocal.	Med
US bladder transabdominal	3		None
FDG-PET whole body	2	Indicated for suspected nodal or distant metastasis.	High
US bladder transrectal	2		None
US bladder transurethral	2		None
Rating Scale: 1=Least appropriate, 9=Most appropriate			***Relative Radiation Level**

Note: Abbreviations used in the tables are listed at the end of the "Major Recommendations" field.

Variant 3: Superficial TCC – no invasion with risk factors.

Radiologic Procedure	Rating	Comments	RRL*
CT urography	8		Med
X-ray intravenous urography	5	Utilization of intravenous urography has continued to decline with the increasingly widespread use of CT urography.	Low
X-ray chest	5		Min
CT abdomen and pelvis with contrast	3	Visceral/nodal status evaluated during CT urography.	High
FDG-PET whole body	1		High

Radiologic Procedure	Rating	Comments	RRL*
US bladder transrectal	1		None
CT chest	1		Med
US bladder transabdominal	1		None
US bladder transurethral	1		None
MRI abdomen and pelvis	1		None
Rating Scale: 1=Least appropriate, 9=Most appropriate			***Relative Radiation Level**

Note: Abbreviations used in the tables are listed at the end of the "Major Recommendations" field.

Summary of Literature Review

Transitional cell carcinoma (TCC) of the bladder accounts for 95% of all bladder cancer in the United States. It is the second most common genitourinary malignancy and the fifth leading cause of cancer deaths in American males over 75 years of age. In 2006, approximately 61,420 new cases were expected to occur. Bladder cancer occurs about four times more commonly in men than in women and with double the frequency in whites compared to African Americans. According to the American Cancer Society, "An estimated 13,060 deaths will occur in 2006. For all stages combined, the 5-year relative survival rate is 82%. When diagnosed at a localized stage, the 5-year survival rate is 94%; 75% of cancers are detected at this early stage. For regional and distant stages, 5-year relative survival rates are 48% and 6%, respectively. Beyond 5 years, survival continues to decline, with a rate of 75% at 10 years and 70% at 15 years after diagnosis." Patients who have been diagnosed and treated for TCC require follow-up evaluation, which is usually based upon the type of treatment as well as accurate initial grading and staging of the tumor.

The purposes of follow-up imaging evaluation are to detect new or previously undetected tumor, to detect recurrent or metastatic disease, and to monitor the effects and/or complications following urinary diversion surgery. Recommendations for tumor surveillance can be based on the classification of patients into three groups; 1) those with superficial bladder cancer but no additional risk factors and treated by local therapy; 2) those with superficial bladder cancer with additional risk factors but still treated by local therapy; and 3) those with invasive bladder cancer, usually treated with cystectomy.

In patients with newly diagnosed TCC, the median time to the first recurrence is 31 months. Subsequent recurrences present with increasing frequency.

The likelihood of recurrent or metastatic disease increases with the presence of one or more of the following risk factors:

1. **Depth of invasion** - Most TCCs of the bladder (75 to 85%) are superficial. Although the risk of recurrence is approximately 75%, most remain superficial, with only 10% to 15% progressing to invasive carcinoma. There is evidence to indicate that cancers that invade the lamina propria (stage T1) should not be regarded as superficial. High-grade stage T1 tumors may progress to invade muscle in 30% to 50% of cases. When this occurs, the prognosis is as poor as it is for those presenting initially with invasive cancer. More than 50% of patients who are treated locally for invasive cancer manifest distant metastases, and they usually die of their disease within 2 years.
2. **Tumor size** - Various studies have shown that tumors greater than 3 cm have up to a 35% chance of progression, and tumors greater than 10 grams are also associated with a poor prognosis.
3. **Grade** - Progression from grade I to III in patients without interval intravesical chemotherapy, cystectomy, or radiation therapy has been associated with an increased incidence of invasive disease and a decreased 5-year survival. In one study, fewer than 10% of grade I tumors but as many as 50% of grade II tumors and more than 80% of grade III tumors were found to be invasive at the time of initial diagnosis. In another study, the 5-year survival of patients with grade I tumors was 94%, but only 40% for patients with grade III tumors.
4. **Adjacent or remote bladder mucosal changes** - If there are adjacent or distant changes of atypia or dysplasia, there is a significant chance of progression to muscle invasion (more than 30% within four years of diagnosis). Carcinoma in situ (CIS), in patients with low-grade, low-stage lesions may be associated with progression to muscle invasion (greater than 80% within 4 years of diagnosis).
5. **Multiplicity of foci** - The finding of multiple tumors is seen in approximately 30% of cases and is associated with a recurrence rate that is almost one-third higher than it is in patients with single lesions. This finding is generally associated with a shortening of the average time until recurrence. Two of three patients with single lesions but nine of ten with multiple lesions developed recurrent carcinoma. In a randomized clinical trial evaluating the prognostic factors associated with recurrence of T1 cancers, the number of tumors (worst for those with three or more) at the time of presentation was most important followed, in order of importance, by the number of recurrences (significantly greater chance of future recurrence for those patients with more than one recurrence per year) and the size of the largest tumor (worst for those over 3 cm).
6. **Upper tract obstruction** has been associated with a decreased 5-year survival rate. Patients with bilateral hydronephrosis had a 5-year survival of 31%, compared with 45% for those who had unilateral involvement and 63% for those with no hydronephrosis.
7. **Lymphatic invasion** in the lamina propria is a very poor prognostic sign, and most patients so affected die within 6 years. Solid (nonpapillary) lesions have a greater tendency for lymphatic invasion.

8. **TCC involvement of the prostate** - When TCC of the bladder is associated with involvement of the prostate (and it has been observed in 29% to 43% of cystectomy specimens), particularly with stromal invasion, there is a substantially increased risk of urethral recurrence. Sixty-seven percent of men with urethral recurrence had prostatic TCC in cystectomy specimens. Urethral recurrence can be expected in only 1% to 4% of cases when there is no TCC in the prostate. Those patients who are not candidates for cystoprostatectomy with urethrectomy are best followed up with urethral washings. Urethroscopy is performed in those having positive cytologic results.
9. **Laboratory tests and chromosomal abnormalities** - A number of laboratory tests have been used to prognosticate tumor progression. These include tests for Thompson-Friedenreich (T) antigen expression, lectin-binding carbohydrate structures, ABH blood group antigens, oncofetal protein expression, and epidermal growth factor receptors. According to one study, "these tests have not been adopted into clinical practice to influence treatment decisions in individual patients." Chromosomal abnormalities in tumors (marker chromosomes and a large proportion of aneuploid tumor cell lines) have also been used to predict tumor recurrence or progression.

Cystoscopic and Virtual Cystoscopic Surveillance

Recommended surveillance for patients treated for superficial bladder TCC includes cystoscopy every 3 months for 2 years, then every 6 months for 2 years, and then yearly thereafter. There has been interest in developing virtual cystoscopic or cystographic techniques using magnetic resonance imaging (MRI) and computed tomography (CT) both for problem solving in cases that are suboptimal for standard cystoscopy (narrow-necked diverticula) and as a way to avoid the patient discomfort associated with standard cystoscopy. One study demonstrated CT cystography to have a 100% sensitivity in identifying 0.5 cm masses and a sensitivity of 95% for all patients in detecting neoplasm with an accuracy of 88%. Another study examined MR cystography (multiplanar reconstructions) and cystoscopy demonstrating a combined sensitivity and specificity of 90.7% and 94.0% respectively. Multiplanar MR reconstructions (cystography) alone demonstrated sensitivity of 92.3% and specificity of 91.1% and MR cystoscopy demonstrated sensitivity of 90.7% and specificity of 90.4%. Both CT and MR cystoscopy provide views comparable to standard cystoscopy.

Urinalysis and cytologic evaluation should be performed at the time of each cystoscopy. Positive cytologic findings are followed by examination of the remaining bladder or upper tracts. There has been interest in developing quantitative tests to complement or even replace urinary cytology in follow-up of bladder carcinoma. One study demonstrated 85% sensitivity in detecting recurrent bladder cancer using the NMP22 marker detection device versus 41% sensitivity for traditional cytology, suggesting that it may substitute for urinary cytology. Additional studies demonstrate similar sensitivities for detecting bladder cancer with various molecular markers and some of these studies suggest that, due to its sensitivity, immunohistochemical testing may increase the time period between cystoscopies or even replace cystoscopy.

Intravenous pyelography (IVP) was once the most common imaging modality used to evaluate the urothelium of the upper collecting system. CT urography has

begun to supplant IVP as its use becomes increasingly widespread. Although some suggest an upper urinary tract imaging study such as these every one or two years, most believe that, in the absence of risk factors, urine cytologic evaluation and cystoscopy are sufficiently accurate, especially since the risk of upper-tract TCC in all patients treated for bladder carcinoma is only about 2%–5% and the mean interval between initial treatment of bladder tumor and detection of subsequent upper-tract cancer is 70-80 months. This low risk may not be sufficient to justify routine upper-tract screening, in spite of the fact that not all recurrences give positive cytologic results or are associated with hematuria.

In a study limited to patients who had their initial bladder cancer treated with radical cystectomy only, the mean interval between cystectomy and detection of upper tract tumors was approximately 40 months (range 8-100). Surveillance of the upper tracts is appropriate in patients with positive urine cytologic results or every one to two years in patients with the following risk factors (usually post-cystectomy):

1. **Carcinoma in situ (CIS)** - When found in the cystectomy specimen, patients had a 9% to 13% incidence of upper tract TCC, with a correlation between the extent of the CIS and the risk of upper tract TCC.
2. **Urethral CIS** - When present, the likelihood of upper tract TCC increases to 20 to 30%.
3. **Multiple tumors**.
4. **Recurrent tumors**.
5. **Tumors involving the ureteral orifices**.
6. **Tumors arising in bladder diverticula** as a result of later detection and earlier transmural tumor extension.

If a documented recurrence is invasive, the patient is then staged.

If CT urography cannot be done if there is incomplete visualization or nonvisualization of the collecting structures, evaluation can be supplemented with retrograde pyelography or, in those patients with ileal conduits, replaced by loopogram. CT urography is also promising in those patients with urinary diversions and may provide additional diagnostic information as it provides examination of the entire abdomen and pelvis unlike a standard loopogram. A preliminary study demonstrated that CT urography with 3D rendering depicted both normal and abnormal postoperative findings in patients with urinary diversions. The addition of digital radiography enhanced visualization of the urinary collecting system to a statistically significant degree. Antegrade pyelography is uncommon but occasionally performed for diagnosis when the above techniques fail or if the collecting system is directly accessed to perform urine cytology or nephroscopy.

Modern imaging techniques have led to more accurate tumor staging and detection of recurrences. These results in stage migration as patient with "...silent or early metastases, [move] from lower into higher..." TNM (tumor, nodes, metastases) categories. When CT is used to evaluate patients following cystectomy, the pelvis is the most common site of recurrence. In these cases, the CT should include evaluation of the abdomen and perineum so that unsuspected, isolated abdominal metastases and recurrent perineal tumor will not be missed. Most metastases are detected within the first 18 to 24 months following surgery.

Bladder cancer deaths occur within 2 years of the initial diagnosis in over 80% of cases. The most common sites of metastatic TCC are lymph nodes, liver, lung, bone, and adrenal glands.

Computed Tomography

CT is recommended at 6, 12, and 24 months for follow-up of patients with minimal muscle invasion (T2) who either elect cystectomy or other types of therapy without cystectomy, since most recurrences become evident within the first 2 years after surgery. There is a different recommendation for follow-up of patients treated with a bladder-preserving surgery. In these patients with transurethral resection of localized muscle-invasive TCC and follow-up combined neoadjuvant chemotherapy and radiation therapy, CT scans of the abdomen and pelvis are performed at 3 months after completion of radiation therapy and then every 6 months or "as otherwise indicated."

Magnetic Resonance Imaging

MRI of the bladder may be used to evaluate of superficial bladder tumors. CT provides limited visualization of the depth of tumor invasion within the bladder wall. MRI, even without intravenous contrast enhancement, has been noted to be "superior to clinical staging" and to allow distinction between advanced T3a tumors and the less invasive T1, T2, and early T3a lesions. One study demonstrated staging accuracies of 85% and 82% in differentiating superficial from muscle-invasive tumors and organ-confined from non-organ-confined tumors, respectively. Additionally, the accuracy of pathologic lymph node detection was 96%. Overstaging occurred in 32% of cases. Another study reviewed 71 patients using gadolinium-enhanced endorectal surface coil and reported an 83% overall staging accuracy. Muscle invasion was diagnosed with 87% accuracy, 91% sensitivity, and 87% specificity.

Although more costly than CT, MRI is more accurate in differentiating between T3b and T4a, between T4a and T4b, and between marrow and no marrow infiltration. MRI performed with ferumoxtran-10 (ultrasmall superparamagnetic iron oxide) contrast demonstrated accuracies in pathologic lymph node detection of up to 92% and sensitivities of up to 96%. These improved techniques for detecting new, recurrent, or metastatic tumors in patients with proven invasive TCC have sometimes been associated with decreased morbidity, although not with increased curability.

Ultrasonography

Abdominal and transurethral ultrasonography (US) have had "limited success" in the evaluation of bladder cancer for determining its local extent. Transabdominal US has "important limitations," particularly for tumors that are flat, smaller than 5 mm, or near the bladder neck and when there has been both understaging and overstaging. However, using transrectal US (TRUS), it is possible to detect almost all lesions in the region of the bladder neck and dome, as well as a number of small tumors (<5 mm). Some evidence suggests that there is improved bladder tumor staging when TRUS is used in conjunction with MRI. TRUS has also been effective for monitoring tumor response or recurrence following neoadjuvant chemotherapy.

Chest Radiography

Chest radiography (PA and lateral) to search for occult metastases should be obtained at 6, 12, 18, and 24 months and then yearly for up to 5 years following cystectomy. A lung lesion suspected on chest radiography may be appropriately followed by a CT scan of the chest for improved definition.

Positron Emission Tomography

Currently, there is a limited role for positron emission tomography (PET) imaging in the assessment of bladder cancer. According to one study, "It has a high positive predictive value and can be used for problem solving in patients with indeterminate findings on conventional imaging." Another study used PET in 12 patients with histologically proven bladder cancer. "The study demonstrated a true-positive rate of 66.7% and a false-negative rate of 33.3%. PET was able to identify 100% (17/17) of distant metastases (lung, bone, and remote lymph node) as well as 66.7% (2/3) of local pelvic lymph nodes." Therefore, "fluorine-18 fluorodeoxyglucose (FDG-PET) might be useful in detecting perivesical tumor growth or distant metastasis in patients with advanced bladder cancer, and for the early detection of recurrent cancer following therapy, although a major remaining pitfall is the intense FDG accumulation due to excretion in the urine."

Likewise, a review of PET imaging in patients with bladder, prostate, and renal cancer concluded that ^{18}F-FDG is unsuitable for imaging bladder tumors because of its high urinary excretion, although there may be a role in detection of recurrent disease. A study correlating ^{18}F-FDG-PET and CT results in the same patients reported sensitivity, specificity, and accuracy of 60%, 88%, and 78%, respectively, in nodal and metastasis staging, suggesting improved distant metastatic and locoregional node staging. Preliminary studies show that ^{11}C-choline PET when compared with CT promises slightly increased accuracy of lymph node staging (63.0% vs 88.9%, p <0.01) and may avoid false-positive lymph nodes due to reactivity when compared with CT. In addition there is negligible urinary excretion of ^{11}C-choline.

Summary

Routine imaging follow-up is **NOT** indicated for patients with superficial TCC and no invasion of the lamina propria or additional risk factors. Patients with superficial TCC require careful observation and IVP or CT urography every 1-2 years **IF** any of the following risk factors for recurrent tumor are present:

1. Tumor size greater than 3 cm or 10 grams
2. Higher than grade I tumor, or
3. Adjacent or remote bladder mucosal changes or dysplasia or CIS. Additional imaging may be necessary if there are positive urine cytologic findings, hematuria, or abnormal cystoscopy.

Patients with invasive TCC, especially those with evidence of: 1) lymphatic or 2) hematogenous invasion, those with associated 3) dysplasia or 4) CIS in the cystectomy specimen, those with associated 5) urethral TCC, 6) multifocal bladder tumors, 7) recurrent bladder tumors, and 8) tumors in bladder diverticula or 9) involving the ureterovesical junctions--should have an IVP or CT urography every

1-2 years. If IVP is inadequate or not possible, CT urography, loopogram, or pyelography (retrograde or antegrade) can be used as a substitute or supplement. Patients requiring cystectomy for invasive bladder cancer should have an MRI or a CT scan at 6, 12, and 24 months and a chest x-ray at 6, 12, 18, 24, 36, 48, and 60 months postoperatively. If recurrent bladder cancer is found and considered invasive, new staging may be required (see the NGC summary of the ACR Appropriateness Criteria® topic Pretreatment Staging of Invasive Bladder Cancer).

Anticipated Exceptions

Patients treated with bladder-preserving surgery and follow-up neoadjuvant chemotherapy and/or radiation therapy for localized muscle-invasive TCC may require more frequent CT and/or MRI. TRUS may be used in selected cases when it is considered helpful. PET imaging may be helpful in cases of advanced bladder cancer, particularly for detection of regional lymph node spread or distant metastases.

Nephrogenic systemic fibrosis (NSF, also known as nephrogenic fibrosing dermopathy) was first identified in 1997 and has recently generated substantial concern among radiologists, referring doctors and lay people. Until the last few years, gadolinium-based MR contrast agents were widely believed to be almost universally well tolerated, extremely safe and non-nephrotoxic, even when used in patients with impaired renal function. All available experience suggests that these agents remain generally very safe, but recently some patients with renal failure who have been exposed to gadolinium contrast agents (the percentage is unclear) have developed NSF, a syndrome that can be fatal. Further studies are necessary to determine what the exact relationships are between gadolinium-containing contrast agents, their specific components and stoichiometry, patient renal function and NSF. Current theory links the development of NSF to the administration of relatively high doses (e.g., >0.2 mM/kg) and to agents in which the gadolinium is least strongly chelated. The FDA has recently issued a "black box" warning concerning these contrast agents (http://www.fda.gov/cder/drug/InfoSheets/HCP/gcca_200705HCP.pdf).

This warning recommends that, until further information is available, gadolinium contrast agents should not be administered to patients with either acute or significant chronic kidney disease (estimated GFR <30 mL/min/1.73m^2), recent liver or kidney transplant or hepato-renal syndrome, unless a risk-benefit assessment suggests that the benefit of administration in the particular patient clearly outweighs the potential risk(s).

Abbreviations

- CT, computed tomography
- FDG PET, fluorodeoxyglucose positron emission tomography
- Med, medium
- Min, minimal
- MRI, magnetic resonance imaging
- TCC, transitional cell carcinoma
- US, ultrasound

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The recommendations are based on analysis of the current literature and expert panel consensus.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Selection of appropriate radiologic imaging procedures for evaluation of patients with bladder cancer

POTENTIAL HARMS

- The relative radiation level is high for computed tomography (CT) of the abdomen and pelvis and whole body fluorodeoxyglucose positron emission tomography (FDG-PET). CT urography and CT of the chest have a medium relative radiation level.
- Some patients with renal failure who have been exposed to gadolinium contrast agents (the percentage is unclear) have developed nephrogenic systemic fibrosis, a syndrome that can be fatal.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

An American College of Radiology (ACR) Committee on Appropriateness Criteria and its expert panels have developed criteria for determining appropriate imaging examinations for diagnosis and treatment of specified medical condition(s). These criteria are intended to guide radiologist, radiation oncologist, and referring physicians in making decisions regarding radiologic imaging and treatment. Generally, the complexity and severity of a patient's clinical condition should dictate the selection of appropriate imaging procedures or treatments. Only those exams generally used for evaluation of the patient's condition are ranked. Other imaging studies necessary to evaluate other co-existent diseases or other medical consequences of this condition are not considered in this document. The availability of equipment or personnel may influence the selection of appropriate imaging procedures or treatments. Imaging techniques classified as investigational by the U.S. Food and Drug Administration (FDA) have not been considered in developing these criteria; however, study of new equipment and applications should be encouraged. The ultimate decision regarding the appropriateness of any specific radiologic examination or treatment must be made by the referring physician and radiologist in light of all the circumstances presented in an individual examination.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

IMPLEMENTATION TOOLS

Personal Digital Assistant (PDA) Downloads

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Living with Illness

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Jafri SZ, Dinan D, Francis IR, Baumgarten DA, Bluth EI, Bush WH JR, Casalino DD, Curry NS, Israel GM, Kawashima A, Papanicolaou N, Remer EM, Sandler CM, Spring DB, Fulgham P, Expert Panel on Urologic Imaging. Follow-up imaging of bladder carcinoma. [online publication]. Reston (VA): American College of Radiology (ACR); 2007. 9 p. [71 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

1996 (revised 2007)

GUIDELINE DEVELOPER(S)

American College of Radiology - Medical Specialty Society

SOURCE(S) OF FUNDING

American College of Radiology (ACR) provided the funding and the resources for these ACR Appropriateness Criteria®.

GUIDELINE COMMITTEE

Committee on Appropriateness Criteria, Expert Panel on Urologic Imaging

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Panel Members: S. Zafar H. Jafri, MD (*principal author*); David Dinan, MD; Isaac R. Francis, MD; Deborah A. Baumgarten, MD; Edward I. Bluth, MD; William H. Bush, Jr., MDE; David D. Casalino, MD; Nancy S. Curry, MD; Gary M. Israel, MD; Akira Kawashima, MD; Nicholas Papanicolaou, MD; Erick M. Remer, MD; Carl M. Sandler, MD; David B. Spring, MD; Pat Fulgham, MD

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Segal AJ, Choyke PL, Bluth EI, Bush WH Jr, Casalino DD, Francis IR, Jafri SZ, Kawashima A, Kronthal A, Older RA, Papanicolaou N, Ramchandani P, Rosenfield AT, Sandler CM, Tempany C, Resnick MI, Expert Panel on Urologic Imaging. Follow-up imaging of bladder carcinoma. [online publication]. Reston (VA): American College of Radiology (ACR); 2005. 9 p. [54 references]

The appropriateness criteria are reviewed annually and updated by the panels as needed, depending on introduction of new and highly significant scientific evidence.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the American College of Radiology (ACR) Web site.

ACR Appropriateness Criteria® *Anytime*, *Anywhere*™ (PDA application). Available from the ACR Web site.

Print copies: Available from the American College of Radiology, 1891 Preston White Drive, Reston, VA 20191. Telephone: (703) 648-8900.

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- ACR Appropriateness Criteria®. Background and development. Reston (VA): American College of Radiology; 2 p. Electronic copies: Available in Portable Document Format (PDF) from the American College of Radiology (ACR) Web site.
- ACR Appropriateness Criteria®. Relative radiation level information. Reston (VA): American College of Radiology; 2 p. Electronic copies: Available in Portable Document Format (PDF) from the American College of Radiology (ACR) Web site.

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI on March 6, 2006. This NGC summary was updated by ECRI Institute on November 15, 2007.

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